

# Exhibit 2

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

In re Actos (Pioglitazone) Product	*	
Liability Litigation	*	6:11-md-2299
	*	
This Document Applies to all cases	*	JUDGE DOHERTY
	*	
	*	MAGISTRATE JUDGE HANNA

**DEFENDANTS’ OPPOSITION TO PLAINTIFFS’ MOTION TO COMPEL  
PRODUCTION OF DOCUMENTS**

Almost one year ago, the parties in this MDL began a Proof of Concept on predictive coding pursuant to the Court’s Protocol Relating to the Production of Electronically Stored Information (“ESI”) of July 27, 2012. As a result of these efforts, Defendants have produced over 4000 responsive documents at a relevance score of 95 and above as determined by the predictive coding algorithm that was developed through the parties’ efforts. This is in addition to Defendants’ production of approximately 1.7 million documents and 23.6 million pages as a result of its use of the traditional keyword search and manual document review method that began in early 2012.

“[C]omputer-assisted coding should be used in those cases where it will help ‘secure the just, speedy, and inexpensive’ determination of cases in our e-discovery world.” *Da Silva Moore v. Publicis Groupe SA*, 287 F.R.D. 182, 183 (S.D.N.Y. 2012) (quoting Fed. R. Civ. P. 1). Here, further production of documents via predictive coding is not just, speedy, or inexpensive for Defendants. When the parties used a score cutoff of 95, 63 percent of the previously unproduced documents found were nonresponsive. The algorithm, therefore, found a small number of *new* responsive documents that had not been previously produced, even when a high score point was

used. Use of lower score points would require Defendants to spend additional time and money reviewing documents that are even less likely to be responsive.

Undeterred, the PSC has requested that Defendants go through the time and expense of producing additional documents at score ranges of 52 to 94, Motion at 6, which would require Defendants to review well over a half million additional documents seven months before the first trial is set to begin. In advocating for this proposal, the PSC and its proffered expert focus solely on the theoretical question of whether the predictive coding algorithm is able to identify responsive documents regardless of whether Defendants have already produced those documents. Plaintiffs entirely ignore the true question before this Court—whether that algorithm is an efficient method of identifying *new* responsive documents. The parties’ review of the documents with 95+ scores proves that it is not. Accordingly, we have reached the stage where the predictive coding Proof of Concept should end, because “the burden [and] expense of the proposed discovery outweighs its likely benefit.” Fed. R. Civ. P. 26(b)(2)(C)(iii).

### **BACKGROUND**

To put this issue into its proper context, the history of document production in this litigation must be considered. In early April 2012, Defendants began producing documents in the MDL and the Illinois Coordinated Proceedings pursuant to traditional keyword search terms and manual review (“traditional review method”). Defendants’ use of the traditional review method had begun months in advance of that first production, following a meeting with Richard Arsenault, Paul Pennock, and Art Crivella (of the document vendor Crivella West) in October 2011, and a meeting with the Illinois Lead Counsel and Mr. Crivella in February 2012. The initial production in April 2012 included portions of the Investigational New Drug Application (“IND”) and New Drug Application (“NDA”) that had been requested by the PSC and that Defendants agreed to produce voluntarily without a formal Request for Production.

Much to the surprise of Defendants, at the MDL status conference held on April 19, 2012, the PSC informed Defendants that they would not be retaining the services of Crivella West, and were interested in Defendants producing documents according to predictive coding methods rather than the traditional review method that was already well underway. The Court strongly encouraged the parties to come to an agreement on predictive coding. The parties subsequently engaged in good-faith discussions, and ultimately agreed to the Proof of Concept for predictive coding that is set forth in the Court's Protocol Relating to the Production of Electronically Stored Information of July 27, 2012 ("ESI Order").

While the predictive coding process was underway in the MDL, Defendants continued producing documents in Illinois pursuant to the traditional review method. Defendants repeatedly offered those documents to the PSC, even though no Requests for Production had been served in the MDL. The PSC refused to accept any of the Illinois productions until the Special Masters required such productions to be made in the MDL. Defendants began producing the documents culled via the traditional review method to the PSC in early September 2012. To date, Defendants have produced documents from over 160 custodians and data sources in the U.S., Japan, and EU, totaling approximately 1.7 million documents and 23.6 million pages as a result of its use of the traditional review method.

The predictive coding process in this MDL has been lengthier and more costly than Defendants anticipated. It began with the parties meeting for multiple days from August 2012 through October 2012 to collaboratively "train" the predictive coding software by reviewing and coding sample documents. The software built an algorithm based on those efforts. That algorithm was run across materials for the custodians listed in the ESI Protocol, and a scaled

relevance score was assigned to each document, with 0 being least likely to be relevant, and 100 being most likely to be relevant, as estimated by the algorithm.

In April 2013 Defendants agreed to produce documents at a score of 95 or higher. The number of documents in the 95+ scored population was 76,316, of which 68,426 had already been produced to the PSC pursuant to the traditional review method. The number of unreviewed documents at the 95+ score was therefore 7,890, and when those documents' family members were added to Defendants' workflow, the number of documents requiring review increased to 13,843.<sup>1</sup> As provided for in the ESI Order, Defendants reviewed those 13,843 documents for responsiveness. Ultimately, over 4000 of the 13,843 documents were produced. Thus, 63 percent of the documents reviewed were nonresponsive. This high nonresponsive rate shows that the algorithm is not an efficient means of unearthing responsive documents that have not already been produced.

The PSC subsequently requested that all documents at scores of 52 to 94 be reviewed and produced by Defendants. This request would require Defendants to review well over a half million additional documents. Below are the numbers of currently unreviewed documents at various score ranges:

---

<sup>1</sup> The PSC's proffered expert Dr. David Lewis states that Defendants' focus on these family members is misguided because it is unlikely the family members had scores of 95+. *See* Declaration of David D. Lewis, Ph.D. ("Lewis Decl.") (Mot. Ex. 1) ¶ 36 ("[T]he fact that the review policy includes reviewing family members is irrelevant to the question of whether the predictive scores are indicative of relevance."). In making this theoretical point, Dr. Lewis ignores that, as a practical matter, Defendants will be required to review all documents in conjunction with their family members, and where a document family contains nonresponsive material, Defendants will be required to redact such material. This process will be both laborious and costly.

Relevance Score Range	Currently Unreviewed Documents
90–94	12,247
80–94	56,483
70–94	144,021
60–94	290,503
50–94	505,326

When family members of documents with scores of 50–94 are added to the workflow, the total number of documents increases to 643,005.

Defendants opposed the PSC’s request for production at score points of 52 to 94 on the basis that the scores are not an efficient means of identifying new responsive documents, and thus the burden of the proposed discovery outweighs any potential benefit. *See* Fed. R. Civ. P. 26(b)(2)(C)(iii). In an attempt to compromise, however, Defendants proposed on May 28, 2013, that they review documents at a score of 90 to 94 where the following terms are present in those scored documents and will produce any additional responsive material identified: Acto\* OR Metact OR Sonias OR Glustin OR Competact OR Glubrava OR Tandemact OR Duetact OR PPAR OR pio OR glitazone OR TZD OR thiazo\* OR AD-4833 OR AD4833 OR 4833 OR HPPAR OR Glizone OR Pioz OR Zactos OR Raga\* OR glitazar OR ciglitaz\*. The PSC refused this compromise, which necessitated presenting this discovery dispute to this Court.

### ARGUMENT

As courts and commentators have acknowledged, computer-assisted predictive coding is far from perfect and is not appropriate in all litigation. *See, e.g., Da Silva Moore*, 287 F.R.D. at 189 (“The Court recognizes that computer-assisted review is not a magic, Staples-Easy-Button, solution appropriate for all cases.”). While the more “traditional” discovery process is not without its criticisms, predictive coding, too, carries its own overbreadth concerns. Therefore, “computer-assisted review software” should be “trained and the results . . . quality control

verified” so that “the parties and the Court [may] see where there is a clear drop off from highly relevant to marginally relevant to not likely to be relevant documents.” *Id.* at 192. Moreover, to the extent a predictive coding method appears to be reliable, “cost effectiveness and proportionality under Rule 26(b)(2)” remain factors that should be considered in determining whether predictive coding is appropriate. *Id.* at 192.

Here, using the predictive coding algorithm to identify possibly relevant documents with scores between 52 and 94 is not justified for the simple, commonsense reason that the parties *are not working on a blank slate*.<sup>2</sup> This is because Defendants have already produced approximately 1.7 million documents and 23.6 million pages pursuant to the traditional review method, and thus the incremental value of reviewing these additional documents is marginal. Defendants therefore should not be required to review these additional documents. Alternatively, if the Court orders review of any documents at scores below 95, Defendants believe that search terms should be employed to increase the responsiveness rate and the PSC should bear the cost of any such production.

### **1. Proportionality**

Although it is true that Rule 26 defines the scope of discovery as non-privileged information “relevant to any party’s claim or defense” and sets forth that “[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible information,” that Rule also carries a significant caveat:

On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:

---

<sup>2</sup> Dr. Lewis disregards this essential fact when he states that Defendants’ view “make[s] the predictive coding system look arbitrarily bad.” Lewis Decl. (Mot. Ex. 1) ¶ 31.

(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;

(ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or

(iii) ***the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.***

Fed. R. Civ. P. 26(b)(2)(C) (emphasis added); *see also id.* 26(b)(1) (expressly recognizing the proportionality rule by providing: “All discovery is subject to the limitations imposed by Rule 26(b)(2)(C).”); *McPeck v. Ashcroft*, 202 F.R.D. 31, 34 (D.D.C. 2001) (“If the likelihood of finding something was the only criterion [of discoverability], there is a risk that someone will have to spend hundreds of thousands of dollars to produce a single e-mail. That is an awfully expensive needle to justify searching a haystack.”).

While the proportionality rule has been mentioned a great deal in recent years in the e-discovery context, it is a principle that has existed within the framework of the Federal Rules for nearly thirty years. Indeed, as one court noted in 1985:

[The 1983] amendments formally interred any argument that discovery should be a free form exercise conducted in a free for all spirit. Discovery is not now and never was free. Discovery is expensive. The drafters of the 1983 amendments to . . . Rule 26 formally recognized that fact by superimposing the concept of proportionality on all behavior in the discovery arena. ***It is no longer sufficient, as a precondition for conducting discovery, to show that the information sought “appears reasonably calculated to lead to the discovery of admissible evidence.”*** After satisfying this threshold requirement counsel also must make a common sense determination . . . *that the information sought is of sufficient potential significance to justify the burden the discovery probe would impose, that the discovery tool selected is the most efficacious of the means that might be used to acquire the desired information (taking into account cost effectiveness and the nature of the information being sought), and that the timing of the probe is sensible, i.e., that there is no other juncture in the pretrial period when there would be a clearly happier balance between the benefit derived from and the burdens imposed by the particular discovery effort.*



*In re Convergent Techs. Secs. Litig.*, 108 F.R.D. 328, 331 (N.D. Cal. 1985) (emphasis added); see also *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (“[D]iscovery . . . has ‘ultimate and necessary boundaries.’” (quoting *Hickman v. Taylor*, 329 U.S. 495, 507 (1947))).

With these principles in mind, Defendants oppose the PSC’s request that they produce documents at predictive scores of 52 to 94. Given that 63 percent of the 13,843 previously unreviewed documents with a 95+ score were nonresponsive, it is highly probable that the vast majority of the over 500,000 unreviewed documents with scores of 52 to 94 will be nonresponsive. Further, to the extent these additional documents are responsive, the fact of responsiveness says nothing about the *legal significance* of these documents. The PSC’s expert Dr. Lewis acknowledges this very point when he explains: “*It is important to note that predictive scores are **not** a measure of the degree of usefulness or importance of documents. A document of great legal importance and relevance can have a low predictive score because the predictive coding system is unsure if the document is relevant.*” Lewis Decl. (Mot. Ex. 1) ¶ 11 (emphasis in original). Despite stating that it is “pleased with the results generated through the predictive coding process of production of over 4000 documents and 16,000 pages that otherwise would not have been produced but for predictive coding,” Motion at 5, the PSC makes no claim about the “legal importance” of any of these documents. The PSC’s silence on this crucial point indicates that notwithstanding the predictive coding algorithm’s ability to identify responsive documents, its practical value is modest because the algorithm is not likely to identify legally significant documents that Defendants have not already produced. Accordingly, the burden and expense of the discovery proposed by the PSC “outweighs its likely benefit,” Fed. R. Civ. P. 26(b)(2)(C)(iii), and the Motion should be denied.

This result is consistent with the approach another district court recently took when faced with a similar dispute. In *In re Biomet M2a Magnum Hip Implant Products Liability Litigation*, No. 3:12-MD-2391, 2013 WL 1729682 (N.D. Ind. Apr. 18, 2013), the defendant had used a combination of keyword searches and a deduplication process to cull a universe of 19.5 million documents down to 2.5 million. *Id.* at \*1. The defendant then employed predictive coding to identify the relevant documents to be produced from the 2.5 million that emerged from the keyword and de-duplication processes. *Id.* This work took place before the litigation was consolidated into an MDL. *Id.* After creation of the MDL, and with the defendant already on pace to spend \$2,000,000 to \$3,250,000 on discovery costs, the MDL Plaintiffs' Steering Committee sought to compel the defendant to apply a predictive coding algorithm to the 19.5 million documents even though confidence tests run by the defendant indicated that this proposal would yield a "comparatively modest" number of new documents. *Id.* The court found that what the defendant had "done complie[d] fully with the requirements of Federal Rules of Civil Procedure 26(b) and 34(b)(2)," and that the Steering Committee's request to "institute predictive coding at that earlier stage sits uneasily with the proportionality standard in Rule 26(b)(2)(C)." *Id.* at \*2. The court based its rejection of the Steering Committee's proposal on Rule 26's proportionality principle:

It might well be that predictive coding, instead of a keyword search, at Stage Two of the process would unearth additional relevant documents. But it would cost Biomet a million, or millions, of dollars to test the Steering Committee's theory that predictive coding would produce a significantly greater number of relevant documents. Even in light of the needs of the hundreds of plaintiffs in this case, the very large amount in controversy, the parties' resources, the importance of the issues at stake, and the importance of this discovery in resolving the issues, I can't find that the likely benefits of the discovery proposed by the Steering Committee equals or outweighs its additional burden on, and additional expense to, Biomet.

*Id.* at \*3 (citing Fed. R. Civ. P. 26(b)(2)(C)).

This Court should likewise apply the proportionality principle to deny the PSC's Motion. Like the MDL Plaintiffs' Steering Committee in the *Biomet* MDL, the PSC would like Defendants to spend hundreds of thousands of additional dollars to "test [its] theory that predictive coding would produce a significantly greater number of relevant documents." In advocating for its theory, the PSC has made no attempt to quantify the incremental benefit this burdensome and costly undertaking will add to the already voluminous discovery Defendants have produced in this complex litigation. As the *Biomet* court did, this Court should find that "the burden [and] expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(2)(C)(iii).

In addition, reopening document production on the massive scale proposed by the PSC will interfere with the already arduous trial preparation plan laid down by this Court. *See Geiserman v. MacDonald*, 893 F.2d 787, 792 (5th Cir. 1990) (discussing the importance of adhering to court-ordered deadlines). For instance, expert disclosures and expert depositions are scheduled to take place between August 1, 2013 and October 11, 2013, and the first bellwether trial will commence on January 27, 2014. Second Amended Scheduling Order: Pilot Bellwether Program (*First Trial*) at 3–4, 6. In establishing these timelines, this Court noted that "the schedule established herein will place extraordinary burdens on this Court, counsel, and the parties," and that "**THE DEADLINES ESTABLISHED HEREIN SHOULD BE CONSIDERED HARD AND FAST. THEY WILL NOT BE EXTENDED, CONTINUED, OR DELAYED BY THE COURT IN ANY WAY ABSENT EXTRAORDINARILY GOOD CAUSE SHOWN.**" *Id.* at 1 (emphasis in original). Given the severe burden that trial preparations will impose on this Court, counsel, and the parties, the PSC's eleventh-hour request to radically expand the scale of discovery should be denied.

## 2. Cost-Shifting

Within the proportionality structure defined by Rule 26(b), some courts have imposed cost-shifting on requesting parties to encourage them “to carefully consider whether the future electronic [discovery] they have proposed to undertake [is] proportionate to the likely benefit.” *DeGeer v. Gillis*, 755 F. Supp. 2d 909, 930 (N.D. Ill. 2010); *see also* Fed R. Civ. P. 26(b)(2)(B)–(C). If this Court requires Defendants to review documents identified in the predictive coding process at scores of 52 to 94, Defendants propose that the PSC bear the costs of that review. This result is consistent with *In re Biomet*, wherein the court concluded that cost-shifting was appropriate after determining that the discovery sought by the plaintiffs failed to satisfy the proportionality rule. *In re Biomet*, 2013 WL 1729682, at \*3 (“[I]f the Steering Committee wishes production of documents that can be identified only through re-commenced processing, predictive coding, review, and production, the Steering Committee will have to bear the expense.”).

Cost-shifting is also appropriate under the “balancing approach” courts have adopted to address the propriety of cost-shifting. *See Rowe Entm’t, Inc. v. William Morris Agency, Inc.*, 205 F.R.D. 421, 429 (S.D.N.Y. 2002). *Rowe* identified eight factors courts typically consider when deciding whether to shift discovery costs to the requesting party:

- (1) the specificity of the discovery requests;
- (2) the likelihood of discovering critical information;
- (3) the availability of such information from other sources;
- (4) the purposes for which the responding party maintains the requested data;
- (5) the relative benefit to the parties of obtaining the information;
- (6) the total cost associated with production;
- (7) the relative ability of each party to control costs and its incentive to do so; and
- (8) the resources available to each party.

*Id.* None of the *Rowe* factors weighs in favor of requiring Defendants to pay for the PSC to test its predictive coding theory, and several strongly favor cost-shifting.

The first factor supports cost-shifting because the PSC has made no attempt to target their request to particular types of documents or specific issues. Instead, the PSC has made a blanket demand for Defendants to review all documents with a relevance score of 52 or greater, and has rejected Defendants' proposal to improve the responsiveness rate by employing search terms to reduce the pool of documents identified using the predictive coding method alone. Motion at 7.<sup>3</sup> The sprawling scope of the PSC's discovery request thus justifies cost-shifting. *See Rowe*, 205 F.R.D. at 430 ("Where a party multiplies litigation costs by seeking expansive rather than targeted discovery, that party should bear the expense.").

The second and third factors coalesce to support cost-shifting because the PSC has failed to establish that the requested discovery is likely to yield "critical information" that has not previously been made available through Defendants' already ample document production. *See id.* at 430 (finding that second factor "mitigates in favor of imposing the costs of discovery on the plaintiffs" in racial discrimination lawsuit where "there has certainly been no showing that the e-mails [at issue] are likely to be a gold mine" and "[n]o witness has testified, for example, about any e-mail communications that allegedly reflect discriminatory or anti-competitive practices"); *id.* (noting that some cases "have denied discovery of electronic evidence or have shifted costs to the requesting party . . . because equivalent information . . . has already been made available"). The PSC does not contend that it expects the predictive coding algorithm to uncover a "gold mine" of new responsive documents. And the PSC's proffered expert Dr. Lewis recognizes not only that predictive scores do not measure "legal importance," Lewis Decl. (Mot. Ex. 1) ¶ 11, but

---

<sup>3</sup> To the extent that this Court permits the PSC to discover any documents with a relevance score below 95, Defendants request that review of those scored documents be compelled only for documents in which one or more of the following search terms are also present: Acto\* OR Metact OR Sonias OR Glustin OR Competact OR Glubrava OR Tandemact OR Duetact OR PPAR OR pio OR glitazone OR TZD OR thiazo\* OR AD-4833 OR AD4833 OR 4833 OR HPPAR OR Glizone OR Pioz OR Zactos OR Raga\* OR glitazar OR ciglitaz\*.

also that any new documents identified by the algorithm are inevitably going to be “less rich in responsive documents than typical documents” with a given score because most such documents will have already been produced by Defendants using the traditional review method, *see id.*

¶¶ 45–46. These points show that the marginal utility of undertaking the discovery proposed by the PSC is both speculative and likely to be inconsequential. *See McPeck*, 202 F.R.D. at 34 (adopting a “marginal utility” analysis to determine which party should bear the cost of additional electronic discovery proposed by the plaintiff and noting that “economic considerations have to be pertinent if the court is to remain faithful to its responsibility to prevent ‘undue burden or expense’” (citing Fed. R. Civ. P 26(c))).

Lastly, the sixth factor compels expense-shifting because Defendants’ cost of reviewing over 600,000 new documents will undoubtedly be substantial. *See Rowe*, 205 F.R.D. at 431 (finding magnitude of expenses favored cost-shifting where plaintiffs themselves projected that “the costs for [defendant] WMA would be between \$24,000 and \$87,000, for [defendant] Monterey between \$10,000 and \$15,000, for [defendant] CAA between \$60,000 and \$70,000, and for [defendants] SFX and QBQ approximately \$64,000”); *Anti-Monopoly, Inc. v. Hasbro, Inc.*, No. 94-civ-2120, 1996 WL 22976, at \*2 (S.D.N.Y. Jan. 23, 1996) (ordering plaintiff to “pay defendants’ reasonable programming expense to retrieve the requested data” in part because “estimated cost of \$1,680 as to [defendant] Hasbro and \$5-6000 as to [defendant Toys ‘R’ Us] [was] not ‘insubstantial’”). Application of the *Rowe* factors therefore warrants shifting the cost of the requested discovery to the PSC.<sup>4</sup>

---

<sup>4</sup> To the extent that this Court grants the PSC’s request for an evidentiary hearing on these issues, Defendants request the opportunity to first depose the PSC’s putative experts Dr. Lewis and Dr. Forrest.

### **CONCLUSION**

For the forgoing reasons, Defendants respectfully request that this Court deny the PSC's motion to compel production of all responsive documents identified in the predictive coding process at relevance scores of 52 to 94. In the alternative, to the extent this Court requires Defendants to review documents at any scores below 95, the PSC should be required to pay the costs of that review and any production arising from it.

DATED: June 19, 2013

Respectfully Submitted,

/s/ Sara J. Gourley

Sara J. Gourley  
Sherry A. Knutson  
SIDLEY AUSTIN LLP  
1 South Dearborn Street  
Chicago, IL 60603  
(312) 853-7000 (Phone)  
(312) 853-7036 (Fax)  
sgourley@sidley.com  
sknutson@sidley.com

*Attorneys for Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify that on June 19, 2013 I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all parties of record by operation of the Court's electronic filing system.

/s/ Sara J. Gourley\_\_\_\_\_

Sara J. Gourley